

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Evaluation of the effect of Autologous concentrated serum on the histological and clinical characteristics of soft tissue after Horizontal Bone Augmentation and Socket Preservation surgery

#### Protocol summary

##### Study aim

Evaluation of the effect of Autologous concentrated serum on the histological and clinical characteristics of soft tissue after Horizontal Bone Augmentation and Socket Preservation surgery

##### Design

A clinical trial with the parallel intervention group, one-way blind, randomized, random sampling method. The randomization method is simple with a random number table. 10 patients referred to the periodontics ward who required horizontal ridge reconstruction surgery and silent protection on both sides of the ridge were selected and after surgery, on one side of the collagen membrane impregnated with ACS and on the other side only collagen membrane is used. During the first week, the amount of pain and clinical symptoms and 4 months later, histological features will be evaluated.

##### Settings and conduct

The study will be performed in the periodontics department of Tabriz Dental School. 10 patients require horizontal ridge reconstruction surgery and silent protection on both sides of the ridge, on one side of the collagen membrane is impregnated with ACS, and on the other side, only collagen membrane is used. Pain and clinical signs will be monitored during the first week. The evaluator is not aware of the type of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion: The same bone needed for reconstruction on both sides Candidate patients extract teeth on both sides of the jaw, Partial edentulous patients on both sides of the jaw Exclusion: Smokers, pregnant women, systemic diseases, not taking corticosteroids

##### Intervention groups

The intervention group included placement of collagen membrane and bone material impregnated with ACS in the postoperative area. The control group consisted of placement of collagen membrane and bone material

alone in the postoperative area.

##### Main outcome variables

Pain rate, inflammatory symptoms

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180630040290N6**

Registration date: **2022-01-03, 1400/10/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-03, 1400/10/13**

Update count: **0**

##### Registration date

2022-01-03, 1400/10/13

##### Registrant information

##### Name

Amir Reza Babaloo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3428 3025

##### Email address

babalooa@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-02, 1400/10/12

##### Expected recruitment end date

2022-01-30, 1400/11/10

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of Autologous concentrated serum on the histological and clinical characteristics of soft tissue after Horizontal Bone Augmentation and Socket Preservation surgery

**Public title**

Evaluation of the effect of concentrated serum on histological and clinical characteristics of dental tissue

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The amount of bone needed for reconstruction is the same on both sides. Candidate patients extract teeth on both sides of the jaw Partial edentulous patients on both sides of the jaw

**Exclusion criteria:**

smokers Pregnant women

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patients require horizontal ridge reconstruction surgery and Horizontal Bone Augmentation and Socket Preservation surgery

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A random sampling method is available among people referring to the periodontics department of Tabriz Dental School. The method of randomization is simple and its unit is individual. Our tool is to randomize the table of random numbers. Also, treatment was assigned to patients randomly. The type of treatment was identified by code A (intervention) and B (control) and placed inside sealed envelopes; The envelopes were then placed in a bag and shaken. Then, it was accidentally taken out of the bag, and after observing the code, the treatment was given to the patient. The evaluator was not aware of the type of treatment.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The present study is one-way blind and the evaluator will also be is not informed about the type of treatment.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

**Street address**

Central office of Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165687386

**Approval date**

2021-07-12, 1400/04/21

**Ethics committee reference number**

IR.TBZMED.REC.1400.353

**Health conditions studied****1****Description of health condition studied**

Horizontal alveolar bone loss

**ICD-10 code**

K06.3

**ICD-10 code description**

Horizontal alveolar bone loss

**Primary outcomes****1****Description**

Pain measurement

**Timepoint**

During a week

**Method of measurement**

Visual Analogue Scale

**2****Description**

Clinical symptoms

**Timepoint**

During a week

**Method of measurement**

REEDA (Redness, edema, ecchymosis, discharge from the wound, approximation)

## Secondary outcomes

### 1

#### Description

Histological features

#### Timepoint

4 months later

#### Method of measurement

Pathology laboratory

## Intervention groups

### 1

#### Description

Intervention group: Patients in need of horizontal ridge reconstruction surgery and silent protection on both sides of the ridge are selected and placed for implant placement. An ACS-impregnated collagen membrane is then applied to one side. During the first week after surgery, the clinical features of soft tissue such as pain in the area with Visual analogue scale (VAS) and other clinical symptoms such as swelling, redness, sensation of the wound, etc. are evaluated with REEDA index and report results. Becomes. Also, 4 months after surgery during implant surgery, a piece of soft tissue is punched at the implant site and sent to the laboratory to examine the histological characteristics of the soft tissue.

#### Category

N/A

### 2

#### Description

Control group: Patients in need of horizontal ridge reconstruction surgery and silent protection on both sides of the ridge are selected and placed for implant placement. On the opposite side, only the collagen membrane is used. During the first week after surgery, the clinical features of soft tissue such as pain in the area with Visual analogue scale (VAS) and other clinical symptoms such as swelling, redness, sensation of the wound, etc. are evaluated with REEDA index and report results. Becomes. Also, 4 months after surgery during implant surgery, a piece of soft tissue is punched at the implant site and sent to the laboratory to examine the histological characteristics of the soft tissue.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Periodontics, Dental Clinic, Tabriz University of Medical Sciences and Health Services

##### Full name of responsible person

Amirreza Babaloo

##### Street address

Dentistry Faculty of Tabriz, Golgasht Ave, Azadi Blvd

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

##### Phone

+98 41 3335 5921

##### Email

amirrezababaloo@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Parviz Shahabi

##### Street address

Central office No. 2, Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

##### Phone

+98 41 3335 7310

##### Email

parvizshahabi@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tabriz University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Amir reza Babaloo

##### Position

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Dentistry

**Street address**

Dentistry faculty, Tabriz University of Medical Sciences, Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5921

**Email**

amirezababaloo@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Amir reza Babaloo

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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+98 41 3335 5921

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amirezababaloo@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Amir reza Babaloo

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Email**

amirezababaloo@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available